

REMARKS

Claims 1-21 and 26-28 are pending in this application and have been rejected in the Office Action.

Applicant's respectfully requests entry of these amendments in spite of the final Office Action because these amendments address a new objection to the claims that were newly raised in the final Office Action, but did not result from any new amendment to the claims made by Applicant. Moreover, this is the first opportunity Applicant has had to change the claims in response to the new claim objection and the claim amendments do not raise any new issue that would require further consideration or search on the part of the Office.

Claim Objections

The Office has objected to claims 2, 3, 6, 7, 14, and 27 for the reasons noted on page 2 of the Office Action. Even though Applicant disagrees with the objection to the claims since the skilled artisan would have understood the metes and bounds of the claims in light of the specification, Applicant has amended the claims to properly respond to this objection. Accordingly, Applicant respectfully requests removal of this claim objection.

Rejection under 35 U.S.C. § 102(b)

The Office has rejected claims 1-20 and 26 under 35 U.S.C. § 102(b) as being anticipated by Wilson et al. (U.S. Patent Application No. 2002/0099327) for the reasons noted on pages 2-4 of the Office Action. Applicant respectfully traverses this rejection.

Applicant respectfully traverses this rejection for the reasons of record, namely, that the Office has not shown that Wilson et al. describe a tunneler. Just because Wilson et al. describe a multi-lumen catheter that is “capable of being used as a tunneler” does not mean that the skilled artisan would understand that it is used as a tunneler. Indeed, the skilled artisan would understand that it is not used as a tunneler since Wilson et al. specifically disclose in several instances that the catheter 12 is pulled through a tunnel that has already been created. So something else, other than the catheter 12, has already created the tunnel and the catheter 12 is not being used as a tunneler.

Such a conclusion is supported by the attached Rule 132 Declaration. This Declaration is signed by Kelly B. Powers, who is not an inventor of the present application and is not an employee of the Assignee of the present application. Mr. Powers reviewed Wilson et al. and came to the conclusion that in light of its disclosure, and given his knowledge in the art, the skilled artisan would have concluded that the catheter 12 is not used as a tunneler. Mr. Powers also concluded that the skilled artisan would not have used the catheter 12 as a tunneler because it would have been difficult—if not impossible—for the catheter 12 to be pushed into a patient. Rather, it would have to be pulled through a patient, as it would in a tunneling procedure.

Thus, the Office has not shown that Wilson et al. teach every limitation in the rejected claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

Rejection under 35 U.S.C. § 102(e)

The Office has rejected claims 26 under 35 U.S.C. § 102(e) as being anticipated by Wilson '396 (U.S. Patent No. 6921396) for the reasons noted on page 4 of the Office Action. Applicant respectfully traverses this rejection.

Claim 26 contains similar limitations as claim 1. Claim 26 also contains the limitation that the tunneler contains a rigid tunneler shaft. Applicant respectfully traverses the rejection over Wilson '396 for the same reason as Wilson et al.: namely, that the Office has not shown that Wilson '396 describe a tunneler.

Wilson '396 describe a multi-lumen catheter 10 with a connector 12. *See Figure 1 and column 7, lines 28-30.* The connector 12 contains a coupling portion 24 that is configured to securely engage a corresponding coupling portion of a medical device such as a trocar, a syringe, or the like. *See column 8, lines 17-20.* Once the trocar 40 is connected to the catheter using the connector 12, the trocar 40 is used to guide the catheter 10 through the tunnel 106. *See column 8, lines 58-60.*

Thus, as with Wilson et al., the skilled artisan would understand that the catheter 10 is not used as a tunneler since Wilson '396 specifically disclose in several instances that the catheter 10 is pulled through a tunnel 106 using a trocar 40. In fact, most of column 2 of Wilson '396 discusses catheters and tunneling procedures and how a trocar acts as a tunneling device for catheters. Indeed, lines 41-42 of column 2 of Wilson '396 specifically describe that a tunneling device includes a trocar. In light of such a disclosure, it is unlikely that the skilled artisan would have understood that the catheter 10 of Wilson '396 would either act as or be used as a tunneler.

Thus, the Office has not shown that Wilson '396 teach every limitation in the rejected claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

Rejection under 35 U.S.C. § 102

The Office has rejected claim 21 under 35 U.S.C. § 102(e) as being anticipated by Zawacki et al. (U.S. Patent Application No. 2004/067463) for the reasons noted on page 4 of the Office Action. Applicant respectfully traverses this rejection.

The Examiner considers that Zawacki et al. describe a multi-lumen catheter (410) and a tunneler with a tip (430) containing multiple shaft members (440,450) with different lengths. But one with ordinary skill in the catheter art would have understood that the structure illustrated in Zawacki et al. as 410 is only a catheter that could not—and would not—have been used as a tunneler.

Zawacki et al. specifically disclose that the catheter 410 is pulled through a tunnel that has already been created in the desired location of the patient. Zawacki et al. describe that the shape of the venous lumen can be transitioned from a D-shape in the proximal portion to a circular shape in the distal portion. The cross-sectional area is configured for the venous lumen is also standardized to permit all sizes of the catheter to be tunneled subcutaneously during implantation using a single size of tunneling trocar. *See paragraph [0074] (emphasis added).*

In light of all of these disclosures, the skilled artisan would have concluded that a tunnel is created by a tunneler before a catheter 410 is inserted in the tunnel. Thus, the skilled artisan would have concluded that the catheter 410 is not used as a tunneler. In other words, the skilled artisan would have understood that since a tunnel already exists when the catheter 410 is used, there would have been no reason to use the catheter 410 as a tunneler.

Such a conclusion is supported by the attached Rule 132 Declaration. This Declaration is signed by Kelly B. Powers, who is not an inventor of the present application and is not an employee of the Assignee of the present application. But Mr. Powers is an inventor of Zawacki

et al. Mr. Powers concludes that in light of the disclosure of Zawacki et al., and given the general knowledge known to one with ordinary skill in the art, the skilled artisan would have concluded that the catheter 410 is not used as a tunneler. Mr. Powers also concluded that the skilled artisan would not have used the catheter 410 as a tunneler because it would have been difficult—if not impossible—for the catheter 410 to be pushed into a patient. Rather, it would have to be pulled through a patient, as it would in a tunneling procedure.

Thus, the Office has not shown that Zawacki et al. et al. teach every limitation in the rejected claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

#### Rejection under 35 U.S.C. § 103

The Office has rejected claim 21 under 35 U.S.C. § 103 as being unpatentable over Imran (U.S. Patent No. 5964796) in view of Vardi et al. (WO 02/076333) for the reasons noted on pages 5-6. Applicant continues to traverse this rejection.

The Office alleges that Imran discloses “a gripping means 21.” *See Office Action at 4.* Applicants respectfully disagree. A review of Imran reveals that feature 21 is described by Imran as merely a body of an introducer sheath. *See column 3, lines 19-30.* Figure 2 illustrates feature 21, and based on that Figure, it is highly unlikely that the skilled artisan would consider feature 21 as a “gripping means.” The Office has pointed to no disclosure in Imran that would have led the skilled artisan to believe that body 21 contains a gripping means other than the mere allegation that tunneler 12 contains a gripping means (21). And the Office has not argued, much less alleged, that Vardi et al. describe such a limitation. And since the Office has not

substantiated that either reference teaches this feature, it is unlikely that the Office can show that their combination teaches such a feature.

Nor it is likely that the skilled artisan would have modified Imran as proposed by the Office. The Office proposes to modify the device of Imran to have introducer shaft members with different lengths. But Imran teaches that his introducer contain tubular members 31 that are sized to contain two catheters 13. *See column 4, lines 41-49.* These two catheters 13 are designed to have the same mechanical characteristics. *See column 5, lines 53-54.* Thus, the skilled artisan would have concluded that the tubular members 31 containing these similar catheters 13 should likewise have similar characteristics. And since the tubular members 31 should be similar, the skilled artisan would have had no reason to follow the Office's proposed modification of making them with different lengths. Indeed, there would have been no motivation to follow the proposed modification and make tubular members 31 with different lengths since that teaches away from the disclosure of Imran.

Thus, neither Imran nor Vardi et al., either alone or in combination, disclose or suggest each and every element of the claimed invention. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

Rejection under 35 U.S.C. § 103

The Office has rejected claims 27-28 under 35 U.S.C. § 103 as being unpatentable over Wilson '396 in view of Zawacki et al. for the reasons noted on page 6. Applicant respectfully traverses this rejection.

As noted above, the Office has not shown that either Wilson '396 or Zawacki et al. describe a tunneler, as recited in the claims. And since the Office has not substantiated that either cited reference teaches this feature, it is unlikely that the Office can show that their combination teaches such a feature.

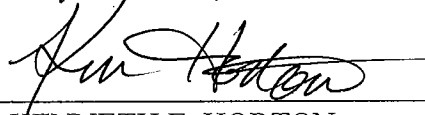
Thus, neither Wilson et al. nor Zawacki et al., either alone or in combination, disclose or suggest each and every element of the claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

#### CONCLUSION

For the above reasons, as well as those of record, Applicant respectfully requests entry of the proposed claim amendments, consideration of the Rule 132 Declaration, and withdrawal of the pending grounds of rejection.

If there is any fee due in connection with the filing of this Amendment, including a fee for any extension of time not accounted for above, please charge the fee to our Deposit Account No. 50-0843.

Respectfully Submitted,

By   
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